AMENDMENTS TO THE CLAIMS

This listing of claims replaces all prior versions, and listings, of claims in the application.

1.-23. (Canceled)

24. (Currently Amended) A method of producing a stable, sterile pharmaceutical formulation comprising lyophilized azithromycin, which method comprises:

(a) preparing a liquid composition comprising an ethanolate of Azithromycin, an acid, and an aqueous solvent,

(b) chilling the composition to a temperature from about -10° C to about 15° C, wherein the temperature is maintained for at least about 20 minutes to about 2 hours,

(c) freezing the composition to a temperature of from about -30° ~~-10°~~ C to about -50° ~~-70°~~ C, to produce a frozen mixture, wherein the temperature is maintained for at least about 1 hour ~~30 minutes to about 20 hours~~,

(d) subjecting the frozen mixture to a primary drying stage, which comprises applying a vacuum to reduce the pressure by an amount effective to remove aqueous solvent from the frozen mixture, and, while applying the vacuum, changing the temperature of the frozen mixture to a primary drying temperature, wherein the primary drying temperature is from about 0° ~~30°~~ C to about 20° C, and wherein the primary drying temperature is maintained for at least about 20 ~~15~~ hours to about 40 ~~50~~ hours, to produce a first intermediate, and

(e) subjecting the first intermediate to a secondary drying stage, which comprises applying a vacuum to reduce the pressure by an amount effective to remove aqueous solvent from the first intermediate, and, while applying the vacuum, (i) changing the temperature of the first intermediate to a first secondary drying temperature, wherein the first secondary drying temperature is from about 20° ~~0°~~ C to about 40° ~~45°~~ C, and wherein the first secondary drying temperature is maintained for at least about 10 ~~5~~ hours to about 20 ~~30~~ hours, and (ii) changing the temperature of the first intermediate to a second secondary drying temperature, wherein the second secondary drying temperature is from about 30° ~~0°~~ C to about 50° ~~60°~~ C, and wherein the second secondary drying temperature is maintained for at least about 10 ~~5~~ hours to about 20 ~~30~~ hours, to produce the pharmaceutical formulation,

wherein ethanol is present in an amount from about 0.005% to about 0.5% by weight of the pharmaceutical formulation.

25. (Original) The method of claim 24, wherein the composition is chilled to a temperature from about 0° C to about 10° C.

26. (Canceled)

27. (Currently Amended) The method of claim 24 ~~26~~, wherein the composition is frozen to a temperature of about -40° C.

28.-29. (Canceled)

30. (Currently Amended) The method of claim 24 ~~29~~, wherein the primary drying temperature is about 8° C.

31. (Canceled)

32. (Currently Amended) The method of claim 24 ~~31~~, wherein the primary drying temperature in the primary drying stage is maintained for at least about 36 hours.

33. (Original) The method of claim 24, wherein the primary drying stage is carried out at a pressure of about 200 micron Hg or less.

34. (Original) The method of claim 33, wherein the primary drying stage is carried out at a pressure of about 80 micron Hg.

35. (Canceled)

36. (Currently Amended) The method of claim 24 ~~35~~, wherein the first secondary drying temperature is about 35° C.

37. (Canceled)

38. (Currently Amended) The method of claim 24 ~~37~~, wherein the second secondary drying temperature is about 45° C.

39. (Original) The method of claim 24, wherein the temperature of the frozen mixture in the secondary drying stage is changed at a rate of about 1° C per minute or less.

40. (Original) The method of claim 39, wherein the temperature of the frozen mixture in the secondary drying stage is changed at a rate from about 0.05 to about 0.1° C per minute.

41. (Canceled)

42. (Currently Amended) The method of claim 24 ~~41~~, wherein the first secondary drying temperature in the secondary drying stage is maintained for at least about 15 hours.

43. (Canceled)

44. (Currently Amended) The method of claim 24 ~~43~~, wherein the second secondary drying temperature in the secondary drying stage is maintained for at least about 18 hours.

45. (Original) The method of claim 24, wherein the secondary drying stage is carried out at a pressure of about 200 micron Hg or less.

46. (Original) The method of claim 45, wherein the secondary drying stage is carried out at a pressure of about 80 micron Hg.

47.-49. (Canceled)

50. (Original) The method of claim 24, wherein the composition is aseptically filtered and aseptically filled into a container after the completion of step (a) and before the completion of step (b).

51.-65. (Canceled)